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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/668,430	09/22/2003	John F. Shanley	P038	2375

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Intellectual Property Department
CONOR MEDSYSTEMS, INC.
1003 HAMILTON COURT
MENLO PARK, CA 94025

EXAMINER	
YABUT, DIANE D	

ART UNIT	PAPER NUMBER
3734	

MAIL DATE	DELIVERY MODE
09/25/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/668,430	SHANLEY, JOHN F.	
	Examiner	Art Unit	
	Diane Yabut	3734	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12 July 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-53* is/are pending in the application.

4a) Of the above claim(s) *29,30 and 36-40* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-28, 31-35, 41-53* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

This action is in response to applicant's amendment received 12 July 2007.

The examiner acknowledges the amendments made to the claims.

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

2. Claims 1, 4-5, 10, 15-18, 20, 23-26, 28, 31-35, 41, 44-45, and 50-53 are rejected under 35 U.S.C. 102(a) as being anticipated by **Hossainy** (U.S. Patent No. **6,558,733**).

Hossainy discloses a stent having a plurality of openings filled with beneficial agents. Specifically, Hossainy discloses a cylindrical device which is expandable, and having end holes at opposite ends of the device, the substantially cylindrical device comprising a plurality of deformable members and non-deformable members, a first plurality of openings containing a first beneficial agent on first and second ends of the cylindrical device; a second plurality of openings containing a second beneficial agent positioned on a central portion of the cylindrical device, wherein the second beneficial agent can be different than the first beneficial agent, wherein the first openings and the second openings are positioned on the non-deformable members. See Hossainy, Figure 4a, col. 5, lines 28-30.

The beneficial agents can comprise different forms of the same drug. See e.g. Hossainy, col. 4, line 41 -col. 5, line 19.

A side hole can be considered to be the circular section that joins adjacent filaments 22 (Applicant's claim 17) in Figure 4a, which has a center axis substantially perpendicular to a longitudinal axis of the device body. Hossainy further discloses interconnected struts 24 and bridging elements (e.g. 22), and the first and second openings are formed in the struts and bridging elements, respectively or otherwise, depending on which openings are defined as the "first and second" openings. See Fig. 4a.

Hossainy discloses the related method of positioning the device. See col. 3, lines 55-65.

Further, the openings can be different sizes. See col. 5, lines 25-28. The openings can be formed by a laser. See Abstract. The holes can have different shapes. Cf. Figs. 5a-6.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

4. Claims 2-3, 6, 11, 14, 19, 21-22, 27, 42-43, and 46 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Hossainy**, as applied to claims 1, 10, 17, 20, 25, and 41 above, in view of Vallana et al., U.S. Patent No. **6,699,281** ("**Vallana**").

Hossainy does not specifically disclose that the drug itself has a different concentration. However, Vallana discloses that it is well known in the art to implant drugs having different concentrations in a stent. See Vallana, col. 8, lines 15-30; Figs. 10A-10D. Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to vary the concentration, and thus the eluting profile, of the agents within the stent openings.

5. Claims 7-8, 12, and 47-48 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Hossainy**, as applied to claims 1, 10, 17, 20, 25, and 41 above, in view of Welsh et al., U.S. **2005/0278016** ("**Welsh**").

Hossainy does not specifically disclose coating the stent with a third beneficial agent, nor using paclitaxel. However, Welsh discloses that it is well known in the art to coat the stent with a beneficial agent (¶ 0144), and that paclitaxel is commonly used as a beneficial agent (¶ 0078). Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to incorporate a third beneficial agent on the exterior of the stent, or to use paclitaxel as the first beneficial agent, in view of the teachings of Welsh.

6. Claims 9, 13, and 49 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Hossainy**, as applied to claims 1, 10, 17, 20, 25, and 41 above, in view of Schreeder et al., U.S. **2002/0007209** ("**Schreeder**").

Hossainy does not specifically disclose using rapamycin. However, Schreeder discloses that it is well known in the art to use rapamycin as a beneficial agent (¶ 0152). Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to use rapamycin as the first beneficial agent, in view of the teachings of Schreeder.

Response to Arguments

7. Applicant's arguments filed 12 July 2007 have been fully considered but they are not persuasive.

8. The applicant generally argues that Hossainy discloses filaments and interconnecting members that are expected to deform during expansion and does not disclose providing depots (which are not through-openings) only in one of the filaments or the interconnecting members, and also teaches away from the use of through openings on the grounds that too deep of an opening will reduce the structural integrity of the filament or interconnecting element. The examiner disagrees. As seen in Figure 4a, there is a non-deformable section 24 and deformable sections (22) in between the non-deformable section. Since the stent deforms radially – expanded and contracting radially – only the filaments 22 are deforming, and are being supported by the interconnecting members 24. Also, in response to applicant's argument that the

reference teaches away from through openings, it is noted that the features upon which applicant relies (i.e., "through openings") are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. What is recited in the claims is "a plurality of openings," and the depots or "pores" 30 read on this limitation.

9. Applicant's arguments with respect to claim 17 have been considered but are moot in view of the new ground(s) of rejection.

10. Applicant also argues that Vallana does not disclose providing a uniform distribution of a drug. The examiner disagrees. In col. 8, lines 15-30 Vallana teaches applying drugs at the ends of the stent, as well as the central area of the stent, which reads on the limitation of providing a uniform distribution of a drug.

11. Lastly, the applicant argues that Welsh only teaches that it is possible to provide biocompatible coatings such as lubricious coatings on the stent, not that a beneficial agent if coated on a stent. The examiner disagrees. A lubricious coating may be considered a beneficial drug, which usually comprises a non-toxic, hydrophilic polyurethane, since it reduces patient trauma.

Conclusion

12. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Diane Yabut whose telephone number is (571) 272-6831. The examiner can normally be reached on M-F: 9AM-4PM EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Hayes can be reached on (571) 272-4959. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

DY

MICHAEL J. HAYES
SUPERVISORY PATENT EXAMINER